

# **EXHIBIT 2**

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF PUERTO RICO**

GERARDO CAMPOS, ET AL.,	:	
	:	
Plaintiffs,	:	CASE NO. 3:12-cv-01529-PAD
	:	
v.	:	
	:	
SAFETY-KLEEN SYSTEMS, INC., ET AL.,	:	
	:	
Defendants.	:	

**DEFENDANT SAFETY-KLEEN SYSTEMS, INC.’S OPPOSITION TO PLAINTIFFS’  
MOTION FOR SUMMARY JUDGMENT/OBJECTION TO MOTION TO STRIKE DR.  
PETER SHIELDS UNDER FEDERAL RULE OF EVIDENCE 702 AND *DAUBERT***

COMES NOW Defendant, SAFETY-KLEEN SYSTEMS, INC., by and through its undersigned attorneys, and files this Opposition to Plaintiffs’ Motion for Summary Judgment/Motion to Strike Dr. Peter Shields Under Federal Rule of Evidence 702 and *Daubert* (ECF No. 111):

**I. BACKGROUND & SUMMARY OF THE ARGUMENT**

Plaintiffs claim Gerardo Campos’ (“Campos”) workplace exposure to benzene allegedly present in Safety-Kleen’s 105 Virgin Solvent (“SK 105”) caused his development of chronic myelogenous leukemia (“CML”). SK 105 is a parts-washing solvent comprised of a refined petroleum distillate, commonly referred to as mineral spirits or Stoddard solvent, which Safety-Kleen historically acquired from major petroleum refiners.<sup>1</sup> No industry or governmental organization has identified mineral spirits, such as SK 105, as a carcinogen.<sup>2</sup> As with other refined petroleum distillates, benzene may appear in mineral spirits as a naturally-occurring, trace contaminant.<sup>3</sup>

Plaintiffs purportedly now move for summary judgment as to benzene’s ability to cause

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<sup>1</sup> Safety-Kleen Systems, Inc.’s Opposing Statement of Material Fact (“OSMF”) No. SK 1.

<sup>2</sup> OSMF Nos. SK 2, SK 9 and SK 10.

<sup>3</sup> OSMF No. SK 3.

CML and simultaneously seek to exclude Safety-Kleen expert Dr. Peter Shields using a variety of red herring arguments.<sup>4</sup> For the reasons discussed herein, this Court must deny Plaintiffs' Motion.<sup>5</sup> Dr. Shields complied with *Daubert* and its progeny in developing opinions utilizing a reliable methodology that fits the facts of this case. Plaintiffs challenge Dr. Shields' conclusions only. However, *Daubert* is not concerned with the generated conclusions.<sup>6</sup> Rather the *Daubert* inquiry focuses solely on the principles and methodology that underlie a proposed opinion.<sup>7</sup> Plaintiffs' sole basis for seeking to strike Dr. Shields is a single comment made in a deposition in a different case involving a different disease process and diesel exhaust where there is no basis whatsoever to determine the context of the remark.<sup>8</sup> The remark is completely unrelated to Dr. Shields' methodology in this case and is an irrelevant consideration for *Daubert*. Dr. Shields' methodology complies with *Daubert* and its progeny and he should not be stricken or limited in any manner.

Weighing the credibility of an expert utilizing methodologically sound principles to generate his opinions is within the purview of the jury and is a question of weight that should be determined by the trier of fact.<sup>9</sup> As such, Plaintiffs' attack, in addition to being an improper

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<sup>4</sup> Plaintiffs' Motion seeks summary judgment without specifying what cause of action Plaintiffs seek summary judgment on and without setting forth any elements of any particular cause of action for which they seek summary judgment. The Motion improperly confuses the concepts of general and specific causation. Safety-Kleen objects to Plaintiffs' Motion as it fails to comply with Federal Rule of Civil Procedure 56(a), is not sufficient pleading to provide notice as to what claims or part of each claim or defense for which summary judgment is being sought.

<sup>5</sup> Safety-Kleen incorporates by reference, as if fully set forth herein, the arguments, authorities, and exhibits to its Motion for Summary Judgment (ECF No. 113), Safety-Kleen's Motion to Exclude the Testimony, Opinions and Report of David F. Goldsmith, Ph.D. and related Reply brief (ECF Nos. 93 and 123), Safety-Kleen's Motion to Exclude the Testimony, Opinions and Report of Dr. Arthur Frank and related Reply brief (ECF Nos. 95 and 125), and Safety-Kleen's Motion to Exclude the Testimony, Opinions and Report of Melvyn Kopstein, Ph.D. and related Reply brief (ECF Nos. 97 and 124).

<sup>6</sup> *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 594-595 (1993); *Bado-Santana v. Ford Motor Co.*, 364 F.Supp.2d 79, 85 (D.P.R. 2005).

<sup>7</sup> *Id.*

<sup>8</sup> Declaration of Dr. Peter G. Shields, at 2, July 15, 2014, attached hereto as Exhibit "A".

<sup>9</sup> *Daubert v. Merrell Dow Pharmaceuticals, Inc.* 509 U.S. 579, 590, 596 (1993); see also *Ruiz Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998). If an expert changes an observation/opinion expressed prior to the pending litigation, such change goes to the weight a trier of fact gives to the expert's testimony, not admissibility. See *Hennessey v. Secretary of Dept. of Health and Human Services*, 2009 WL 1709053 \*1, \*44 n.141 (Fed. Cl. 2009).

challenge under *Daubert*, is premature and is properly suited for cross-examination at trial, if at all. Finally, aside from not presenting a proper challenge under *Daubert* and its progeny, Plaintiffs' Motion to Strike is untimely and should not be considered by this Court.

Plaintiffs also move for a summary judgment determination that benzene exposure causes CML. That is not the issue in this case. The general causation issue for this court to determine is whether benzene *as a component of mineral spirits* can cause CML. Mineral spirits are not benzene.<sup>10</sup> The fact that tiny amounts of benzene may appear in mineral spirits as a trace contaminant does not support a conclusion that mineral spirits have the same toxic effect as benzene.<sup>11</sup> Plaintiffs fail to provide reliable expert testimony to carry their burden of proof to show that the tiny amount of benzene, if any, in SK 105 is capable of causing CML.<sup>12</sup> Further, Dr. Shields opined unequivocally that there is no evidence to suggest benzene, let alone the tiny amounts of benzene in SK 105, causes CML. Moreover, Safety-Kleen's expert witnesses Dr. David Pyatt and Dr. David Garabrant have also opined that there is no consistent evidence in the scientific community to support a conclusion that benzene, much less SK 105, is capable of causing CML. Both doctors employ a reliable methodology, *which is unchallenged by Plaintiffs*<sup>13</sup>, and will testify at trial in support of Safety-Kleen's general and specific causation defense. Based upon the foregoing arguments, Plaintiffs' request for summary judgment must be denied.

This Opposition/Objection is based upon the pleadings on file with this Court, the pertinent case law, Safety-Kleen's Opposing Statement of Material Facts<sup>14</sup> and attached exhibits

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<sup>10</sup> OSMF No. SK 3.

<sup>11</sup> *Henricksen v. ConocoPhillips Company*, 605 F.Supp.2d 1142,1176 (E.D. Wash 2009) (excluding plaintiffs' causation experts because "[n]one of the studies relied upon have concluded that gasoline has the same toxic effects as benzene, and none have concluded that the benzene component of gasoline is capable of *causing* AML.") (Emphasis in original). It is noteworthy the court made this statement regarding gasoline, which contains up to 4.9% benzene, or 49,000 ppm benzene. *Id.* at 1150.

<sup>12</sup> OSMF Nos. SK 5 and SK 6.

<sup>13</sup> OSMF No. SK 11.

<sup>14</sup> Filed concurrently herewith pursuant to Local Rule 56(c) & (e).

filed simultaneously herewith and expressly incorporated by reference as if set forth herein.

## II. MEMORANDUM OF LAW

### A. DR. SHIELDS METHODOLOGY COMPORTS WITH *DAUBERT* AND ITS PROGENY

Plaintiffs' Motion to Strike Dr. Shields pursuant to *Daubert* is improper.<sup>15</sup> Dr. Shields employed a reliable methodology fitting the facts of this case in accordance with the parameters set forth by *Daubert* and its progeny. Plaintiffs' sole argument, that Dr. Shields believes benzene causes CML, is misleading, false, based solely upon a single statement made in error, in a deposition in a different case regarding a different substance and a different disease process.<sup>16</sup> Most importantly and according to *Daubert*, this is not a valid basis to strike Dr. Shields. *Daubert* evaluates an expert's methodology – *how* the expert reaches his or her conclusion – and is completely unconcerned with the conclusion itself.<sup>17</sup>

#### 1. Dr. Shields' employed a reliable, scientifically accepted methodology, admissible under *Daubert*, in offering his opinions in this case.

In formulating his opinions in this case, Dr. Shields undertook a comprehensive review of different types of scientific data in order to assess whether mineral spirits, like SK 105, is capable of causing CML.<sup>18</sup> Plaintiffs' Motion ignores the sources and methodology set forth in his report and discussed in his deposition in this case. Since Plaintiffs alleged that Mr. Campos was exposed to benzene, even though Mr. Campos did not use benzene and there are only trivial amounts of benzene in SK 105, Dr. Shields also assessed whether benzene exposure can cause CML.<sup>19</sup> Dr. Shields applied the scientifically-accepted Bradford-Hill criteria in formulating his

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<sup>15</sup> Safety-Kleen notes Plaintiffs filed a four-page Motion that refers to an attached Memorandum of Law. It is unclear whether the "Argument" section of Plaintiffs' Motion is the Memorandum of Law referenced. However, no other pleading was filed with the Court. Safety-Kleen's Opposition/Objection is limited to the arguments raised by Plaintiffs in their Motion and Statement of Material Facts.

<sup>16</sup> Exhibit A, Shields Decl. at 2.

<sup>17</sup> *Daubert*, 509 U.S. at 594-595; *Bado-Santana*, 364 F.Supp.2d at 85.

<sup>18</sup> Report of Dr. Peter G. Shields, pg. 13-17, 25-29, Feb. 28, 2014 (hereinafter "Shields Report"), attached hereto as Exhibit B.

<sup>19</sup> *Id.* at 26-29.

opinions in this case.<sup>20</sup> Dr. Shields reviewed the scientific literature studying benzene exposure and CML, including dozens of epidemiological studies, in order to determine whether a causal link exists.<sup>21</sup> To the extent Plaintiffs seek to challenge Dr. Shields' opinions pursuant to *Daubert*, it is the methodology outlined above that Plaintiffs must attack.<sup>22</sup> Tellingly, Plaintiffs' Motion does not address Dr. Shields' methodology at all.

Instead, Plaintiffs' Motion discusses a single comment Dr. Shields made in a 2008 deposition. The testimony in question comes from *Batton*, a case having to do with a railroad worker who allegedly developed myelodysplasia / myelodysplastic syndrome ("MDS"), a pre-leukemic hematological disorder, as a result of exposure to diesel exhaust.<sup>23</sup> In response to a question whether benzene causes any forms of leukemia in humans, Dr. Shields replied that it was his belief that benzene can cause AML and CML. The statement occurred in the middle of questioning related to benzene's ability to cause MDS in humans. There was no follow-up. If any follow-up had been done at the time, Dr. Shields would have corrected his misstatement.<sup>24</sup> CML was not mentioned again during the remainder of the deposition.<sup>25</sup> And when Dr. Shields later spent two days providing trial testimony in the case, the topic of CML was never discussed.<sup>26</sup> Dr. Shields did not undertake a review the benzene/CML literature in preparation for his *Batton* deposition as he was not retained to discuss that particular issue.<sup>27</sup> Dr. Shields does not recall the context for his off-the-cuff comment, nobody followed-up on the remark in deposition or trial, and nobody relied on the remark.<sup>28</sup>

## **2. Dr. Shields' opinions are consistent and based on reliable methodology.**

<sup>20</sup> *Id.* at 14-17; Shields Dep. 18:6-19:1, May 9, 2014, attached hereto as Exhibit C; *Milward v. Acuity Specialty Products Group, Inc.*, 639 F.3d 11, 17 (1st Cir. 2011)(discussing Bradford-Hill criteria).

<sup>21</sup> Exhibit B, Shields Report at 28-29; Exhibit C, Shields Dep. 14:5-15:16, 61:14-24.

<sup>22</sup> *Daubert*, 509 U.S. at 594-595; *Bado-Santana*, 364 F.Supp.2d at 85.

<sup>23</sup> Exhibit A, Shields Decl. at 2.

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

In 2006, two years before his *Batton* deposition, Dr. Shields was retained in a case where the plaintiff alleged that exposure to benzene caused his CML.<sup>29</sup> As in this case, Dr. Shields undertook an extensive review of the available literature specific to benzene and CML, which is thoroughly discussed in his report.<sup>30</sup> Following his review, he concluded, that there was “insufficient human data to opine that benzene causes a measureable increase in CML at any dose.”<sup>31</sup> *Christopher* was the first time that Dr. Shields was retained in a benzene/CML case.<sup>32</sup> The present case is only the second; and it is the first time Dr. Shields has offered oral testimony in a benzene/CML case.<sup>33</sup> Dr. Shields is a leading expert on the issue of cancer/leukemia causation. The fact that he has only been retained twice in his career in benzene/CML cases is illustrative of the fact that the scientific literature does not support a link between benzene and CML. If it did, Dr. Shields would have been retained in more than two benzene/CML cases.

Plaintiffs remark in this Motion and their prior briefing that Dr. Shields agrees with Plaintiffs’ experts’ that benzene causes CML. The argument is completely disingenuous and belies Dr. Shields’ opinions, which were developed both here and in the *Christopher* case utilizing *Daubert* compliant methodologies.<sup>34</sup> In both cases, Dr. Shields performed a comprehensive review of all relevant and reliable benzene/CML literature in order to determine if a causal association existed between benzene exposure and CML.<sup>35</sup> Dr. Shields does not recall why he made the comment in *Batton* or his basis for doing so.<sup>36</sup> He does know that there is no time in which there were consistent, statistically significant findings in the benzene/CML

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<sup>29</sup> *Id.* at 1.

<sup>30</sup> Report of Dr. Peter Shields in *Christopher v. Consolidated Rail Corporation*, at 7-14, 18-24, Aug. 24, 2006, Exhibit A, Shields Dec. at Ex. 1 (hereinafter “Shields *Christopher* Report”).

<sup>31</sup> *Id.* at 27.

<sup>32</sup> Exhibit A, Shields Decl. at 1.

<sup>33</sup> *Id.* at 1-3; Exhibit B, Shields Report at 4-32.

<sup>34</sup> Exhibit B, Shields Report at 13-17, 25-29; Exhibit C, Shields Dep. 14:5-15:16, 18:6-19:1, 61:14-24; Exhibit A-1, Shields *Christopher* Report at 7-14, 18-24; Exhibit A, Shields Decl. 1-4.

<sup>35</sup> The literature showed no relationship between benzene and CML. Exhibit A-1, Shields *Christopher* Report at 27; Exhibit B, Shields Report at 31-32; Exhibit C, Shields Dep. 17:10-24.

<sup>36</sup> Exhibit A, Shields Decl. at 2.

literature.<sup>37</sup> Accordingly, the statement in *Batton* must have been made in error.<sup>38</sup> Dr. Shields made a single, unprepared remark in a diesel fuel/MDS deposition, and Plaintiffs have no means whatsoever to determine the context of that comment. *Daubert* evaluates the context.<sup>39</sup> *Daubert* considers the underpinnings of a comment, opinion, or conclusion but *Daubert* is ultimately unconcerned with the conclusion itself.<sup>40</sup>

Safety-Kleen further takes exception to Plaintiffs' misleading representations that Dr. Shields creates new opinions to support whatever party hires him.<sup>41</sup> This case and *Christopher* are the only times Dr. Shields has been retained to opine regarding benzene's ability to cause CML. Because the literature has consistently and conclusively illustrated that benzene exposure does not cause CML, his opinion has remained consistent.<sup>42</sup> On both occasions he utilized a meticulous methodology in accordance with *Daubert*. An isolated off-the-cuff remark, which was completely irrelevant to his opinions in the *Batton* case, is not evidence that Dr. Shields is catering to a particular party's agenda.

Critiquing conclusions or remarks without the context of the underlying methodology is not relevant to the *Daubert* inquiry.<sup>43</sup> Plaintiffs ignore the sources and methodology set forth in Dr. Shields' report and discussed in his deposition in the instant case (which mirror his methods in the *Christopher* case). Similarly, Plaintiffs' Motion ignores the lack of sources and absence of any methodology for the irrelevant and erroneous answer given in Dr. Shields' 2008 *Batton* deposition. They then ask the Court to take the illogical leap that the misstatement from 2008 is the truth, despite the fact that there's no evidence to allow that opinion to stand under *Daubert*.

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<sup>37</sup> *Id.* at 2.

<sup>38</sup> *Id.*

<sup>39</sup> *Daubert*, 509 U.S. at 594-95; *Bado-Santana*, 364 F.Supp.2d at 85.

<sup>40</sup> *Id.*

<sup>41</sup> The party who hired him did not benefit from his comment in *Batton*. Exhibit A, Shields Decl. at 2.

<sup>42</sup> Retention in benzene CML cases is so rare because the science is especially bad for Plaintiffs. Exhibit A, Shields Decl. at 2.

<sup>43</sup> *Daubert*, 509 U.S. at 594-95.



### 3. Cross-Examination is Plaintiffs' platform to critique Dr. Shields.

Striking Dr. Shields pursuant to *Daubert* would be improper. Plaintiffs do not critique the methodology Dr. Shields used to develop his opinion, nor do they critique the literature or other support materials Dr. Shields relied upon in reaching his opinions. Plaintiffs' sole critique of Dr. Shields comes down to the comment from the *Batton* deposition. To the extent the comment is relevant at all, which Safety-Kleen argues it is not, it is not properly challenged via *Daubert*. Rather, at most this is purely a question of weight of evidence or credibility of the expert. Determining witness credibility and evidentiary weight are within jury's province.<sup>44</sup> The proper forum to assess Dr. Shields' credibility as a witness is in front of the jury, through cross-examination, where the jury will have the opportunity to assess the weight to be given to Dr. Shields' testimony.<sup>45</sup>

### 4. Plaintiffs' untimely Motion should be denied on procedural grounds.

Parties must file *Daubert* objections in accordance with established deadlines or have good cause justification for their failure to comply.<sup>46</sup> A party's failure to timely file *Daubert* motions waives that party's right to bring a *Daubert* challenge.<sup>47</sup> This Court initially set March 21, 2014 as the deadline for motions to limit or preclude expert testimony and May 16, 2014 as

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<sup>44</sup> *Seahorse Marine Supplies, Inc. v. Puerto Rico Sun Oil Co.*, 295 F.3d 68, 81 (1st Cir. 2002)(citing *Mitchell v. United States*, 141 F.3d 8, 16-17 (1st Cir. 1998).

<sup>45</sup> *Id.*

<sup>46</sup> *Feliciano-Hill v. Principi*, 439 F.3d 18, 24 (1st Cir. 2006) (district court on "firm ground" rejecting an untimely *Daubert* motion because "*Daubert* generally contemplates a 'gatekeeping' function, not a 'gotcha' junction"). In *U.S. v. Diaz*, 300 F.3d 66 (1st Cir. 2002), the Court stated "litigants must raise a timely objection to the validity or reliability of expert testimony under *Daubert* in order to preserve a challenge on appeal to the admissibility of that evidence." See also *United States v. Gilbert*, 181 F.3d 152, 162-63 (1st Cir.1999) (declining to consider *Daubert* validity challenge to admitted expert testimony where no objection was made to the trial court on that basis); see also *Galderma Laboratories, L.P. v. Aquent, Inc.*, 2009 WL 498113, \*1, \*6 (N.D.Tex. 2009) (failure to file a *Daubert* motion by deadline in court's scheduling order constituted waiver); *Gray v. Energy XXI GOM LLC*, 2013 WL 4011990, \*1, \*5 (M.D.La., 2013) (*Daubert* motion denied as untimely because not filed in accordance with scheduling order); see also *Mendez v. Banco Popular de Puerto Rico*, 900 F.2d 4, 7 (1st Cir. 1990) ("A district judge must be firm in managing crowded dockets and demanding adherence to announced deadlines."); *Rosario Rivera v. PS Group of Puerto Rico, Inc.*, 186 F.Supp.2d 63, 66 (D.P.R. 2002) ("It is essential that a court's deadlines be followed in order to allow for the proper management of the court's caseload."); Local Rule 16 (j)(1); F.R.C.P. 16.

<sup>47</sup> *Feliciano-Hill*, 439 F.3d at 24; *Galderma Laboratories, L.P. v. Aquent, Inc.*, Civ.A. 4:06-cv-822-7, 2009 WL 498113, \*1, \*6 (N.D.Tex. Feb. 27, 2009); *Gray v. Energy XXI GOM LLC*, Civ. A. 12-165-JJB, 2013 WL 4011990, \*1, \*5 (M.D.La. Aug. 5, 2013)

the dispositive motion deadline.<sup>48</sup> On February 21, 2014, the parties made a joint motion to the Court requesting that the *Daubert* deadline be moved from March 21 to the parties' stipulated deadline of May 16, 2014.<sup>49</sup> Subsequently, on April 4, 2014, at the request of the parties, the Court entered an Order extending the dispositive motion deadline to June 13, 2014—neither the parties' request nor the April 4th Order altered the May 16, 2014 *Daubert* deadline.<sup>50</sup>

Plaintiffs' Motion to Exclude Dr. Shields was filed June 13, 2014, nearly a month after the agreed upon deadline for motions to limit or preclude expert testimony. Plaintiffs' Motion contains no mention as to why the Motion was filed after the deadline or evidence that would illustrate good cause justifying their delay. Nor did Plaintiffs seek an extension of time to file their *Daubert* motions as directed by Local Rule 6 and 16(j).<sup>51</sup> As there is no justification for Plaintiffs' delay, Plaintiffs' Motion to Exclude must be stricken from the record.

**B. PLAINTIFFS' REQUEST FOR SUMMARY JUDGMENT IS IMPROPER AND LACKS SUPPORTIVE AUTHORITY**

Plaintiffs are not entitled to summary judgment. This is not a situation where Plaintiffs have satisfied their initial burden, and it is incumbent upon Safety-Kleen to illustrate genuine issues of material fact in order to survive summary judgment. Rather, Plaintiffs make the unsupported argument that a single misstatement by a defense expert in an unrelated case six years ago waives their burden of proof and Safety-Kleen's defenses. Plaintiffs offer no other justification for their entitlement to summary judgment.<sup>52</sup> A toxic tort plaintiff must prove both

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<sup>48</sup> ECF Nos. 53 and 54. Note that throughout the entirety of the case, separate deadlines have existed for motions to preclude or limit expert testimony and dispositive motions.

<sup>49</sup> See Joint Agreed Motion To Set Deadline For Filing Motion To Limit Or Preclude Expert Testimony (ECF No. 79). On March 4, the Court referred the Joint Motion to extend the *Daubert* deadline to Magistrate Judge McGiverin but also indicated that the Motion was granted. See Order Re 79 Motion For Miscellaneous Relief (ECF No. 82). Regardless, this Court has specifically ordered that the parties are to abide by all stipulated deadlines. ECF No. 54.

<sup>50</sup> ECF Nos. 90 and 92.

<sup>51</sup> Local Rule 6 and 16(j).

<sup>52</sup> Plaintiffs' Motion seeks summary judgment without specifying what cause of action Plaintiffs seek summary judgment on and without setting forth any elements of any particular cause of action for which they seek summary judgment. The Motion improperly confuses the concepts of general and specific causation. Safety-Kleen objects to

general causation (that the alleged toxin is capable of causing the disease at issue in humans) and specific causation (that the alleged toxin did, in fact, cause the plaintiff's disease),<sup>53</sup> both of which involve scientific assessments that must be established through expert testimony.<sup>54</sup> As set forth in full in Safety-Kleen's own Motion for Summary Judgment, Plaintiffs have failed to proffer admissible evidence to meet their burdens on both general and specific causation.<sup>55</sup> Moreover, Dr. Shields misstatement in no way pertains to specific causation.

Assuming *arguendo*, Plaintiffs brought forth admissible evidence of general causation *and* specific causation that satisfied their burden of proof, *and* prevailed on striking Dr. Shields, Safety-Kleen would still be entitled to present evidence from its other designated experts on general and specific causation; therefore, summary judgment is improper.

### **1. Plaintiffs cannot establish general or specific causation.**

Plaintiffs impermissibly ask the Court to presume causation based on a statement Dr. Shields' made in error six years ago, in an unrelated case; there is no law that supports such a

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Plaintiffs' Motion as it fails to comply with Federal Rule of Civil Procedure 56(a), is not sufficient pleading to provide notice as to what claims or part of each claim or defense for which summary judgment is being sought.

<sup>53</sup> *Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671, 677 (6th Cir. 2011); *Sterling v. Velsicol Chem. Corp.*, 855 F.2d 1188 (6th Cir. 1988); *Bonner v. ISP Techs. Inc.*, 259 F.3d 924, 928 (8th Cir. 2001) ("[t]o prove causation in a toxic tort case, a plaintiff must show both that the alleged toxin is capable of causing injuries like that suffered by the plaintiff in human beings subjected to the same level of exposure as the plaintiff, and that the toxin was the cause of the plaintiff's injury"); *see also* Federal Judicial Center, *Reference Manual on Scientific Evidence* 627 (3d. ed. 2011) (defining specific causation as "whether exposure to an agent was responsible for a given individual's disease.") As to specific causation, the plaintiff must show (1) dose-response relationship, (2) temporality, (3) absence of confounders, and (4) coherence. Dose-response refers to an exposure to the toxic substance at a level sufficient to induce the complained-of medical condition. *See Pluck*, 640 F.3d at 677; *see also Kelley v. American Heyer-Schulte Corp.*, 957 F.Supp. 873, 875 (W.D. Tex. 1997); *Hall v. Baxter Healthcare Corp.*, 947 F.Supp. 1387, 1412-1413 (D. Or. 1996). Temporality refers to the requirement that the exposure to the toxic substance is related in time to the onset of the disease, e.g. the effect did not precede the alleged exposure. *Downs v. Perstorp Components, Inc.* 126 F.Supp.2d 1090, 1095 (E.D. Tenn, 1999).

<sup>54</sup> Numerous district courts in Puerto Rico and throughout the United States require expert testimony to maintain a cause of action in products liability cases such as this one. *Rubio-Gonzalez v. Bridgestone-Firestone, Inc.*, 2006 WL 2715152 (D.P.R. 2006); *Fremaint v. Ford Motor Co.*, 258 F. Supp. 2d 24, 27 ( D.P.R. 2003); *Cruz Vargas v. R.J. Reynolds Tobacco Co.*, 218 F. Supp. 2d 109, 119 (D.P.R. 2002); *Carbalo-Rodriguez v. Clark Equip. Co.*, 147 F. Supp. 2d 66, 71 (D.P.R. 2001); *Collazo-Santiago v. Toyota Motor Corp.*, 937 F. Supp. 134, 137 (D.P.R. 1996). *Pluck*, 640 F.3d at 677; *Baker*, 680 F.Supp.2d at 874; *Clemente v. U.S.*, 422 F.Supp. 564, 569 (D.C.Puerto Rico, 1976) (Reversed on other grounds in *Zabala Clemente v. U.S.*, 567 F.2d 1140 (1<sup>st</sup> Cir. 1977)); *see also* Fed. R. Evid. 702.

<sup>55</sup> ECF No. 113. In the interest of space and to avoid burdening the Court with a restatement of Safety-Kleen's arguments and authorities in support of its Motion for Summary Judgment in this matter, Safety-Kleen refers by reference and incorporates its arguments as if set forth fully herein.

position. Plaintiffs' Motion reflects that benzene is a known risk factor for CML, and that this is accepted by courts and leading authorities; Plaintiffs' own experts' testimony dispute this. Plaintiffs' Motion states that there is no dispute as to general causation; this is disputed, and Plaintiffs still have a burden to prove specific causation.

Benzene is not an agreed upon risk factor for the development of CML.<sup>56</sup> Plaintiffs' own expert Dr. David Goldsmith admitted in his opinion that benzene is a risk factor for CML, does not have general support within the scientific community. He testified that as of "2013, 2014...there's slowly a movement towards seeing that there is *some demonstrable risk* that wasn't there five years ago."<sup>57</sup> He also testified that the "*scientific community is seeing this as something that they need to have more research on*" and are "try[ing] and understand and replicate studies that that suggest that the...risk is moving in a – if you will, a positive direction."<sup>58</sup> Moreover, most cases of CML are idiopathic.<sup>59</sup> The existence of a known risk factor is not enough to create a presumption of causation where most cases of the disease are idiopathic.<sup>60</sup> In *Henricksen*, the court made clear that the existence of a known risk factor ("exposure to benzene") was "not a sufficient basis for ruling out idiopathic origin in a particular case, particularly where most cases of the disease [AML] have no known cause."<sup>61</sup> This is because "[t]he majority (80-90%) of all adult AML cases are *de novo* or idiopathic, with no

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<sup>56</sup> OSMF 4.

<sup>57</sup> Goldsmith Dep. at 82:23-83:2, Apr. 29, 2014, attached hereto as Exhibit D. See *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360 (6th Cir.), cert. denied, 506 U.S. 826, 113 S. Ct. 84, 121 L. Ed. 2d 47 (1992) (finding no scientific basis for testimony of a causation expert who did "not testify on the basis of the collective view of his scientific discipline, nor [did] he take issue with his peers and explain the grounds for his difference"); *O'Conner v. Commonwealth Edison Co.*, 807 F. Supp. 1376, 1398 (D. Ill. 1992), aff'd 13 F.3d 1090 (7th Cir.), cert. denied 129 L. Ed. 2d 838, 114 S. Ct. 2711 (1994) (holding that "an expert opinion that actually contradicts directly the scientific consensus is inadmissible"); *Conde v. Velsicol Chem. Corp.*, 804 F. Supp. 972, 1024 (S.D. Ohio 1992), aff'd 24 F.3d 809 (holding that "when an expert expresses an opinion which is not generally accepted within the medical and scientific communities, he has an obligation to provide a reasoned explanation of why his methodology and opinions differ").

<sup>58</sup> Exhibit D, Goldsmith Dep. 83:6-84:7.

<sup>59</sup> OSMF No. SK 8.

<sup>60</sup> *Henricksen*, 605 F.Supp.2d at 1149, 1162.

<sup>61</sup> *Id.* at 1162.

readily identifiable cause.”<sup>62</sup> Plaintiffs and their experts cannot establish that Mr. Campos’ illness was not idiopathic.<sup>63</sup>

Plaintiffs’ Motion also states that courts and leading medical institutions recognize that CML is caused by benzene and excessive exposure to radiation. In support of this sweeping assertion, Plaintiffs rely upon *one* inapplicable West Virginia case and a string of websites their experts did not rely upon.<sup>64</sup> Contrary to Plaintiffs’ claims, *Casdorph* did not conclude that benzene causes CML.<sup>65</sup> The case was an appeal from an administrative workers’ compensation proceeding in West Virginia, where the court found the claimant brought sufficient evidence to establish his disease was caused by his occupational exposures.<sup>66</sup> The case involved evidentiary standards much less rigorous than those of federal civil court proceedings.<sup>67</sup> The *Casdorph* Court only required a claimant to prove her claim by “proper and satisfactory proof” and that research reflect a ‘clear link’ between the hazard and the disease.<sup>68</sup> Moreover, testimony in that case reflected significant exposure by the Plaintiff to 2-Butoxyethanol, which is independently associated with blood abnormalities and is believed to enhance the toxicity of benzene.<sup>69</sup> With regards to the websites Plaintiffs attach to their Motion, these are not the type of material on which a medical causation opinion can be based.<sup>70</sup> Plaintiffs’ experts’ reports and depositions make no reference to these websites or these institutions as authorities on the cause of cancer. As Dr. Shields pointed out in his deposition, the websites are not peer-reviewed literature and there is no way to assess the context, reliance materials, author, findings, or quality of findings by simply reading a printout from a webpage that provides no context for their purported

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<sup>62</sup> *Id.* at 1149.

<sup>63</sup> ECF No. 113.

<sup>64</sup> *Casdorph v. W. Va. Ins. Commr.*, 690 S.E.2d 102 (W.Va. 2009).

<sup>65</sup> *Casdorph*, 690 S.E.2d 102.

<sup>66</sup> *Id.* at 104.

<sup>67</sup> *Id.* at 107.

<sup>68</sup> *Id.* The term clear link is undefined by this court.

<sup>69</sup> *Id.* at 111.

<sup>70</sup> *See* Fed. R. Evid. 703.

conclusions.

## **2. Dr. Shields misstatement is not evidence of specific causation in this case.**

Plaintiffs have not established specific causation; Dr. Shields' misstatement in the *Batton* case will not meet this burden for them. "To prove causation in a toxic tort case, a plaintiff must show both that the alleged toxin is capable of causing injuries like that suffered by the plaintiff in human beings subjected to the same level of exposure as the plaintiff, *and that the toxin was the cause of the plaintiff's injury.*"<sup>71</sup> The latter component is specific causation, which Plaintiffs have failed to establish.<sup>72</sup> Dr. Shields has not testified that Mr. Campos' illness was caused by exposure to SK 105. Rather he opined, as do Safety-Kleen's other expert witnesses, that there is insufficient evidence to suggest that Mr. Campos' exposures to SK 105 caused his CML.<sup>73</sup>

## **3. Safety-Kleen has two other experts to testify on general and specific causation.**

Even assuming that Dr. Shields' testimony was not available to Safety-Kleen, two other qualified experts are designated to discuss general and specific causation on Safety-Kleen's behalf: Dr. David Pyatt and Dr. David Garabrant. Dr. David Pyatt is a toxicologist with more than 22 years of experience and approximately 100 peer-reviewed publications and abstracts in the fields of environmental and occupational toxicology, experimental hematology, carcinogenesis, and immunology. Among other things, Safety-Kleen designated Dr. Pyatt to testify regarding:

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<sup>71</sup> *Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671, 677 (6th Cir. 2011); *Sterling v. Velsicol Chem. Corp.*, 855 F.2d 1188 (6th Cir. 1988); *Bonner v. ISP Techs. Inc.*, 259 F.3d 924, 928 (8th Cir. 2001) (emphasis added); *see also* Federal Judicial Center, *Reference Manual on Scientific Evidence* 627 (3d. ed. 2011) (defining specific causation as "whether exposure to an agent was responsible for a given individual's disease.") As to specific causation, the plaintiff must show (1) dose-response relationship, (2) temporality, (3) absence of confounders, and (4) coherence. Dose-response refers to an exposure to the toxic substance at a level sufficient to induce the complained-of medical condition. *See Pluck*, 640 F.3d at 677; *see also Kelley v. American Heyer-Schulte Corp.*, 957 F.Supp. 873, 875 (W.D. Tex. 1997); *Hall v. Baxter Healthcare Corp.*, 947 F.Supp. 1387, 1412-1413 (D. Or. 1996). Temporality refers to the requirement that the exposure to the toxic substance is related in time to the onset of the disease, e.g. the effect did not precede the alleged exposure. *Downs v. Perstorp Components, Inc.* 126 F.Supp.2d 1090, 1095 (E.D. Tenn, 1999).

<sup>72</sup> ECF No. 113.

<sup>73</sup> See OSMF No. SK 7.

“liability, causation, evaluation of chemicals at issue in this case, Mr. Campos’ alleged occupational exposure, scientific and peer-reviewed literature pertaining to solvents, the chemicals and diseases alleged in this case, along with all other issues related to this case from a toxicological and epidemiological point of view, among others.”

Dr. David Garabrant is a licensed physician specializing in occupational medicine. He is a specialist in the fields of occupational medicine and internal medicine and in the field of epidemiology, especially as it relates to the study of diseases related to exposures to chemical agents. Safety-Kleen designated Dr. Garabrant to testify on a variety of causation issues, including:

“general principles of occupational medicine and epidemiology and to offer opinions concerning his interpretation of the world’s medical and epidemiological literature regarding the relationship, if any, between petroleum-based products, mineral spirits, benzene or other chemicals and hematopoietic malignancies, including Chronic Myelogenous Leukemia.”

Notably, neither of these experts qualifications or methodology has been challenged by Plaintiffs. Accordingly, Plaintiffs’ Motion for Summary Judgment should be denied as Safety-Kleen has expert evidence in support of its case regardless of the outcome on their Motion to Strike Dr. Shields.

### **C. PLAINTIFFS’ MOTION MISCHARACTERIZES EVIDENCE**

Throughout their Motion, Plaintiffs’ Motion rely upon a single misstatement made by Dr. Shields in the *Batton* case. Not only is this comment is not relevant to any relief sought by Plaintiffs, Plaintiffs mischaracterize this testimony. Plaintiffs have identified the remark in the plural as “prior deposition testimony of the Safety-Kleen *experts*,” “what he previously stated in other *depositions* and what he has truly believed for *decades*,” and “those *comments*.”<sup>74</sup> The remark was a single statement made in error, in one deposition, by one of Safety-Kleen’s experts. The comment is not reflective of beliefs held by Dr. Shields, or the rest of Safety-Kleen’s

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<sup>74</sup> ECF 111, Plaintiffs’ Motion for Summary Judgment/Motion to Strike Dr. Peter Shields Under Federal Rule of Evidence 702 and *Daubert*, at 1, 3, 4 (emphasis added).



experts. The remark was never discussed again in that deposition or in Dr. Shields' trial testimony for that case, was never expressed by Dr. Shields as written or oral testimony elsewhere, and certainly is not an opinion that has been given by any of Safety-Kleen's other experts.<sup>75</sup>

Plaintiffs also indicate that "both specific causation experts in this case, Dr. Arthur Frank for the Plaintiff and Dr. Peter Shields for the Defendant, share the same opinion that benzene causes CML." First, Dr. Shields is not Safety-Kleen's only specific causation expert. Both Dr. Garabrant and Dr. Pyatt offer opinions on specific causation in this case for Safety-Kleen. Second, specific causation in this case, *Plaintiffs' burden to prove*, is whether Mr. Campos' exposures caused his CML. Dr. Shields never testified that Mr. Campos' illness was caused by his benzene exposures. Finally, and as stated above, Dr. Shields does not agree that benzene causes CML.

### **III. CONCLUSION**

For all the reasons set forth herein, Plaintiffs' Motion for Summary Judgment/Motion to Strike Dr. Peter Shields should be denied. The Motion to Strike Dr. Shields is not a proper challenge under *Daubert*, is properly saved for cross-examination at trial, and is untimely. Plaintiffs have failed to provide adequate support illustrating that they are entitled to summary judgment on general causation. Even if Dr. Shields were to be stricken, which he should not be, Safety-Kleen can offer the testimony of other experts in support of Safety-Kleen's general causation opinion.

Respectfully submitted,

JONES CARR M<sup>c</sup>GOLDRICK, L.L.P.

/s/ Amanda M. Koch  
Amanda M. Koch

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<sup>75</sup> Exhibit A, Shields Decl. at 2.



**CERTIFICATE OF SERVICE**

On July 16, 2014, I electronically submitted the foregoing document with the clerk of the court for the U.S. District Court, District of Puerto Rico, using the ECF system. I hereby certify that I have served all counsel and/or *pro se* parties of record electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

By: /s/ Amanda M. Koch  
**Amanda M. Koch**